

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children in intensive care unit

Protocol summary

Study aim

Determination of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children in intensive care unit

Design

Randomized parallel group clinical trial Single blinded
Method of randomization : block Unit of randomization : individual Randomization strata in stratified randomization: age (>/< 1 year) and surgery (upper/lower GI) Tools used in randomization: table of random numbers Allocation concealment will carried out Target sample size: 70

Settings and conduct

Blinding: participants, nurses, Data analyser supplement and placebo will be similar in volume and shape.

Participants/Inclusion and exclusion criteria

Patients undergoing major gastrointestinal surgery at the Akbar Hospital of Mashhad and admitted to the intensive care unit due to medical indications

Intervention groups

Intervention group: Selenium supplementation will continue to be given at a dose of 20 µg / kg / d for 10 days or until discharge from the intensive care unit or death. High-dose selenium content will be injected intravenously 20 cc of dextrose 5% in 60 minutes.
Control group: The placebo(serum: dextrose 5%) with the same volume and shape as the control group will be administered, for 10 days or until discharge from the intensive care unit or death.

Main outcome variables

Pro-oxidant- Antioxidant Balance (PAB) status,
Inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042449N1**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **prospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Fatemeh Roudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2423

Email address

roudif951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-06, 1397/11/17

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of high doses of selenium on oxidative stress status and inflammatory factors in post

gastrointestinal surgery children in intensive care unit

Public title

effect of selenium on oxidative stress status and inflammatory factors in post gastrointestinal surgery children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

0-10 years old patients undergoing major gastrointestinal surgery at the Akbar Hospital of Mashhad Admission to the intensive care unit due to medical indications Filling out the informed consent form by a parent or legal guardian Stability of hemodynamic and metabolic status in the first 24 to 48 hours

Exclusion criteria:

Patients who are not allowed to start a nutrition support care for them within the first 24-48 hours Diagnosed autoimmune disorders Diagnosed cancers Severe sepsis at the admission time History of chemotherapy and radiotherapy in the past month Diagnosed renal failure Diagnosed severe hepatic failure Severe and active bleeding A known case of human immunodeficiency virus Preterm neonates

Age

From **1 day** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization : block Unit of randomization : individual Randomization strata in stratified randomization: age (>/< 1 year) and surgery (upper/ lower GI) Tools used in randomization: table of random numbers Allocation concealment will carried out

Blinding (investigator's opinion)

Single blinded

Blinding description

With the exception of a pharmacist,corresponding physician and investigator the supplement/ placebo assignment will be concealed from the patients, nursing system, data analyser and safety monitoring board throughout the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Campus of University (Paradise Daneshgah), Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

91779-48564

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.553

Health conditions studied

1

Description of health condition studied

Digestive System Surgical Procedures

ICD-10 code

K56.60

ICD-10 code description

Unspecified intestinal obstruction

2

Description of health condition studied

selenium deficiency

ICD-10 code

E64.8

ICD-10 code description

Sequelae of other nutritional deficiencies

3

Description of health condition studied

Congenital diaphragmatic hernia

ICD-10 code

Q79.0

ICD-10 code description

Congenital diaphragmatic hernia

4

Description of health condition studied

Acute abdomen

ICD-10 code

R10.0

ICD-10 code description

Acute abdomen

5

Description of health condition studied

Congenital malformations of esophagus

ICD-10 code

Q39

ICD-10 code description

Congenital malformations of esophagus

6

Description of health condition studied

Other specified congenital malformations of upper alimentary tract

ICD-10 code

Q40

ICD-10 code description

Other congenital malformations of upper alimentary tract

7

Description of health condition studied

Congenital disorders of small intestine

ICD-10 code

Q41

ICD-10 code description

Congenital absence, atresia and stenosis of small intestine

8

Description of health condition studied

Congenital disorders of large intestine

ICD-10 code

Q42

ICD-10 code description

Congenital absence, atresia and stenosis of large intestine

9

Description of health condition studied

Congenital malformations of gallbladder, bile ducts and liver

ICD-10 code

Q44

ICD-10 code description

Congenital malformations of gallbladder, bile ducts and liver

Primary outcomes

1

Description

Pro-oxidant- Antioxidant Balance (PAB) status

Timepoint

before intervention and after 10 days

Method of measurement

Pro-oxidant- Antioxidant Balance (PAB) assay

2

Description

inflammatory factors

Timepoint

before intervention and after 10 days

Method of measurement

Interleukin 1 beta: ELISA, high-sensitivity C-reactive protein (hs-CRP) test: Immunoturbidimetry

Secondary outcomes

1

Description

Serum and urine selenium Level

Timepoint

before intervention and 1, 10 days after intervention

Method of measurement

atomic absorption

2

Description

Serum Glutathione peroxidase level

Timepoint

before intervention and 1, 10 days after intervention

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Selenium supplementation will continue to be given at a dose of 20 µg / kg / d for 10 days or until discharge from the intensive care unit or death. High-dose selenium content will be injected intravenously 20 cc of dextrose 5% in 60 minutes. Injectable selenium in sodium selenite form with a concentration of 50 µg / ml by the Pharmacy school of Mashhad University of Medical Sciences will be used.

Category

Treatment - Other

2

Description

Control group: The placebo (serum: dextrose 5%) with the same volume and shape as the intervention group, for 10 days or until discharge from the intensive care unit or death.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar hospital

Full name of responsible person

Dr. Gholamreza Khademi

Street address

Shahid Kaveh boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

91779-48564

Phone

+98 51 3871 3801

Email

KhademiGH@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Deputy of Research and Technology of the University,
Qoreishi Center, Daneshgah street.

City

mashhad

Province

Razavi Khorasan

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13131 - 99137

Phone

+98 51 3841 1538

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Roudi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

Street address

Mashhad University of Medical Sciences (MUMS)
Campus of University (Paradise Daneshgah), Azadi
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City

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91779-48564

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+98 51 3800 2423

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Email

roudif951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Roudi

Position

PhD student

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Roudi

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Fax

Email

roudif951@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

When the data will become available and for how long

The non-identifiable individual participant data will become available after the publication of the relevant articles.

To whom data/document is available

they will be available for people working in academic institutions and people working in businesses can also apply to receive it.

Under which criteria data/document could be used

The non-identifiable individual participant data can only be used for research.

From where data/document is obtainable

The non-identifiable individual participant data will be obtainable by sending an e-mail to Dr. Mohsen Nematy. (e-mail address: NematyM@mums.ac.ir)

What processes are involved for a request to access data/document

Other researchers in academic institutions can send their request by e-mail to Dr. Mohsen Nematy. The data will be sent to them after consulting and approving the research team.

Comments